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मानक

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IS 3237-3 (1985): Special Purpose Syringes, Part 3: BCG Syringes [MHD 12: Hospital Equipment]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

**SPECIFICATION FOR
SPECIAL PURPOSE SYRINGES REAFFIRMED**

PART 3 BCG SYRINGES 2007

(Second Revision)

1. Scope — Covers requirements for BCG syringe used for BCG injections.

1.1 Unless otherwise stated in this standard, the provisions observed in IS : 3235-1980 'General requirements for syringes for medical use (*first revision*)' shall apply.

2. Types, Shape and Dimensions

2.1 The syringes shall be of the following two types:

Type 1 Glass and metal syringe

Type 2 All glass coloured syringe

2.2 The typical shape of the syringe is shown in Fig. 1.

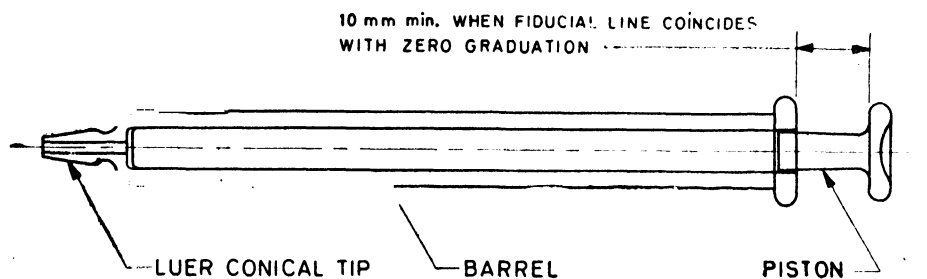


FIG. 1 BCG SYRINGE

2.3 Scale intervals and other critical dimensions for the syringes shall be in accordance with Table 1. The length of the barrel shall be such as to allow at least 25 percent more liquid than the full capacity.

TABLE 1 CAPACITY AND CRITICAL DIMENSIONS OF BCG SYRINGE

Graduated capacity	1 ml
Tolerance on graduated capacity	± 5 percent
Maximum overall length	115 mm
Length of graduated scale	50 mm
Scale intervals	0.01 ml
Numbering of scale intervals	.1, .2, .3, .4, .5, .6, .7, .8, .9, 1 ml
Thickness of glass, <i>Min</i>	1.25 mm

3. Requirements

3.1 Nozzle — The male conical tip of the nozzle shall be of Luer type and shall comply with IS : 3234-1979 'Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (*first revision*)'.

Adopted 31 August 1985

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Gr 2

IS : 3237 (Part 3) - 1985

3.2 Graduations and Numberings — The numbering of scale intervals shall be in accordance with Table 1. The number shall be close to but shall not touch the ends of the graduation mark to which it relates. The numbering shall generally conform to the details given in Fig. 2.

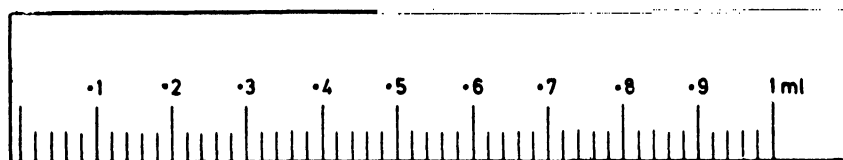


FIG. 2 GRADUATIONS OF BCG SYRINGE

3.3 Piston

3.3.1 Syringe may have piston of metal with silicon rubber ring or of blue glass colour.

3.3.2 Type 2 syringe shall have a piston of blue colour glass.

3.4 Barrel — Type 1 syringe barrel shall be of clear glass as given in IS : 3235-1980. Type 2 syringe barrel shall be of actinic amber colour glass. The amber colour shall be such as to protect the live bacilli stored in the syringe from sun rays. At the same time the piston is easily visible through the actinic coloured glass barrel and the fiducial lines shall be capable of being judged against graduation scale very accurately.

3.5 The effluent shall be of 1 mm to 1.8 mm diameter and it shall be concentric with tip. The tip shall be properly ground to suit the hub of the needle.

4. Tests — All tests, as provided under 8 of IS : 3235-1980 shall apply.

5. Marking — Each syringe shall be legibly and indelibly marked with the following:

- a) Capacity and graduations as specified in Table 1 and Fig. 2;
- b) Means of identification of barrel and piston; and
- c) Manufacturer's name, initials or recognized trade-mark.

5.1 ISI Certification Marking — Details available with the Indian Standards Institution.

6. Packing — Each syringe may be packed as agreed to between the purchaser and the supplier.

7. Sampling — Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However, a recommended sampling plan is given in Appendix A.

APPENDIX A
(Clause 7)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1. Lot

A-1.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimension under similar conditions shall constitute a lot.

A-1.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

Lot Size			Sample Size	Sub-Sample Size
(1)			(2)	(3)
Up	to	100	5	5
101	"	150	8	5
151	"	500	13	8
501	"	1 000	20	13
1 001	"	10 000	32	13
10 001	and above		50	20

**AMENDMENT NO. 1 JANUARY 1991
TO**

**IS : 3237 (Part 3) - 1985 SPECIFICATION FOR
SPECIAL PURPOSE SYRINGES**

PART 3 BCG SYRINGES

(Second Revision)

(Page 1, Table 1, col 2) — Substitute '0.01 ml or 0.02 ml' for '0.01 ml'.

(Page 2, clause 3.2, last sentence) — Substitute the following for the existing sentence:

'Typical graduations and numbering with 0.02 ml scale interval are shown in Fig. 2.'

(MHD 12)

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A-1.2.1 These syringes shall be selected from the lot at random and in order to ensure the randomness of selection procedures given in IS : 4905-1968 'Methods for random sampling' may be followed.

A-2. Number of Tests and Criteria for Conformity

A-2.1 All the syringes selected at random in accordance with col 1 and 2 of Table 1 shall be tested for dimensions, capacity, shock test, leakage test, test for entrapped fluid, and freedom from strain and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.

A-2.2 If the lot is found to be conforming to the requirements given in **A-2.1**, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 2. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.

EXPLANATORY NOTE

This standard has been splitted into several parts during second revision. The following parts have been published while the others are under formulation:

Part 1 Insulin syringes

Part 2 Tuberculine syringes